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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------------|
| 10/757,646 | 01/13/2004 | Tracee Eidenschink | S63.2B-11321-US01 | 3946 |
| 23552 7590 06/12/2007 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 | | | EXAMINER SEVERSON, RYAN J | |
| | | | ART UNIT 3731 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/757,646

Applicant(s)

EIDENSCHINK ET AL.

Examiner

Ryan Severson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15, 21, 22 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15, 21, 22 and 24-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/13/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendments filed 13 March 2007.

Drawings

2. The drawings were received on 13 March 2007. These drawings are accepted.

Claim Rejections - 35 USC § 112

3. The 35 USC 112 2nd paragraph rejection of the previous office action is withdrawn in view of applicant's remarks (see page 11 of the response filed 13 March 2007) regarding the meaning of the term "tecophilic."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1-9, 15, 21, 22, and 24-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Eidenschink et al. (2005/0149161).**

6. The applied reference has a common assignee and inventor (Eidenschink) with the instant application. Based upon the earlier effective U.S. filing date of the reference,

it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

7. Regarding claim 1, Eidenschink reference discloses a catheter assembly with a catheter shaft (116) having a balloon (114) underlying a rotatable sheath (102, see figure 15 and paragraph 59). The sheath has a first portion (183) and a second portion (the middle of the sheath). The inner diameter of the first portion is less than the inner diameter of the second portion (see figure 15). The balloon has a first portion (the distal end) and a second portion (the center). The first portion of the sheath overlies the first portion of the balloon, and likewise the second portion of the sheath overlies the second portion of the balloon.

8. Regarding claim 2, the catheter assembly further includes a guidewire housing (104). The guidewire housing is engaged to the proximal portion of the sheath (see figure 15 and paragraph 58).

9. Regarding claim 3, the catheter assembly further includes a stent (120). The stent is disposed about the sheath (see figure 15).

10. Regarding claim 4, the stent is disposed about a portion of the guidewire housing (see figure 15).

11. Regarding claim 5, the sheath further includes a third section (the proximal end 181). The middle or second section lies between the first and third sections (183 and

181). The inner diameter of the first portion is less than the inner diameter of the second portion.

12. Regarding claims 6-9, both the first and third portions are tapered with inner diameters less than the inner diameter of the second portion. The second portion has an inner diameter that is constant along its length (see figure 15).

13. Regarding claim 15, the device further includes a stent (120) disposed about the sheath (see figure 15) having a plurality of interconnected members defining cell openings.

14. Regarding claims 21 and 22, the sheath has a first end portion (183), a second end portion (181) and an intermediate portion in between (see figure 16). The stent is disposed about the intermediate portion (see figure 16). The outer diameter of the first and second end portions is at least as great as the outer diameter of the stent (see figure 16). The outer diameters of the end portions are capable of being *substantially* equal to the outer diameter of the stent.

15. Regarding claim 24, the stent can be coated with a therapeutic agent (see paragraph 72).

16. Regarding claim 25, the therapeutic agent can be a non-genetic agent including those from the list in the claim (see paragraph 73).

17. Regarding claim 26, the therapeutic agent can be a genetic agent including those from the list in the claim (see paragraph 74).

18. Regarding claim 27, the therapeutic agent can be a cellular material including those from the list in the claim (see paragraph 75).

19. Regarding claim 28, the cellular material can be any of those materials from the claim (see paragraphs 76-106).
20. Regarding claim 29, the therapeutic agent can be a polymer coating including those from the list in the claim (see paragraph 107).
21. Regarding claim 30, the catheter assembly can include a lubricious coating between the sheath and the catheter (see paragraph 65).
22. Regarding claim 31, the sheath can be partially constructed from a hydrophilic material (see paragraph 60).
23. Regarding claim 32, the sheath can be partially constructed from a tecophilic material (see paragraph 61).
24. Regarding claim 33, the sheath can be partially constructed from a first and second material (see paragraph 62).
25. Regarding claim 34, the sheath can be constructed from the materials listed in the claim (see paragraph 63).
26. Regarding claim 35, the first material can be a polymer matrix and the second material a reinforcing material supported within the matrix (see paragraph 62).
27. Regarding claim 36, the polymer matrix can be made from any of the materials listed in the claim (see paragraph 63).
28. Regarding claim 37, the reinforcing material can be any of the materials listed in the claim (see paragraph 64).
29. Regarding claim 38, the sheath has a length less than that of the catheter (see figure 15).

Conclusion

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

31. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 9:00 - 5:30.


33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ryan Severson
June 8, 2007



(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
6/8/07